JUL 18 2003



## SECTION 3: 510(K) SUMMARY

K031477

### APPLICANT'S NAME AND ADDRESS


Ocular Sciences Inc.
1855 Gateway Blvd.
Suite 700
Concord, CA 94520
USA


### Contact Person


Richard Lippman, OD FAAO
Vice President Ophthalmic Regulatory Medical Products
R.P. Chiacchierini & Associates, LLC
15825 Shady Grove Road Suite 30
Rockville, Maryland 20850
Telephone: (240) 683-3738
Fax: (240) 683-9236


### 1. IDENTIFICATION OF DEVICE

| | |
|---|---|
| Common Name: | Hydrophilic Soft Contact Lens |
| Trade Name: | HYDROGENICS® 2.0 60 UV ASPHERE (ocufilcon F) Soft (Hydrophilic) Contact Lens |
| Classification: | Daily Wear Soft (hydrophilic) Contact Lens |
| Device classification: | Class II (21 CFR 886.5925) |

### 2. DESCRIPTION OF DEVICE

HYDROGENICS® 2.0 60 UV ASPHERE (ocufilcon F) Soft (Hydrophilic) Contact Lenses are available with in monomer tint (Vat Blue 6) and with ultraviolet absorbing additive (benzophenone based):

- +10.00 D to -10.00 D Asphere
- with center thickness from 0.025mm to 0.40mm
- with base curves of 8.00mm to 9.20mm
- with diameter of 12.00mm to 18.00mm

The lens material for the HYDROGENICS® 2.0 60 UV ASPHERE (ocufilcon F) is the same as the Biomedics® 60 UV (ocufilcon F) lens in spherical design as described in submission K992264 cleared on November 24, 1999.

The aspheric lens design for the HYDROGENICS® 2.0 60 UV ASPHERE (ocufilcon F) is the same design construct as the BIOMEDICS® UV ASPHERE (ocufilcon D) as cleared in K020193 on February 28, 2002.

The HYDROGENICS® 2.0 60 UV ASPHERE (ocufilcon F) Soft (Hydrophilic) Contact Lens has a spherical posterior surface. The anterior (convex) surface is constructed in lenticular form to provide optimum edge thickness and contour. This front optical surface allows for correction of visual acuity in non-aphakic persons with non-diseased eyes and has been aspherized to control longitudinal spherical aberration of the lens across the power range.

## 3. INTENDED USE

HYDROGENICS® 2.0 60 UV ASPHERE (ocufilcon F) Soft (Hydrophilic) Contact lenses are indicated for the correction of visual acuity in persons with not-aphakic, non-diseased eyes that are myopic (nearsighted) or hyperopic (farsighted) and may exhibit refractive astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

The HYDROGENIC® 2.0 60 UV ASPHERE (ocufilcon F) Soft (Hydrophilic) Contact Lenses are indicated for daily wear. The eye care practitioner may prescribe the contact lenses for either single use disposable wear or for frequent replacement wear. When prescribed for frequent replacement/planned replacement the lenses may be disinfected using a chemical or hydrogen peroxide disinfecting systems.

The HYDROGENICS® 2.0 60 UV ASPHERE (ocufilcon F) Soft (Hydrophilic) Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

## 4. PREDICATE DEVICES

The following predicate lenses were selected to address material (FDA Group IV: high water, ionic polymer), intended use (daily wear) and lens designs (Asphere).

*Lens material, spherical lens design and intended use:*
BIOMEDICS® UV 60 (ocufilcon F) Hydrophilic Contact Lenses for Daily Wear, FDA Group IV, high water content, ionic soft contact lenses are marketed nationally and internationally by OCULAR SCIENCES Inc. under PMA K992264 cleared for marketing on November 24, 1999.

*Asphere lens design:*

BIOMEDICS® UV ASPHERE (ocufilcon D) Soft (hydrophilic) Contact Lens for Daily Wear, FDA Group IV, high water content, ionic soft contact lenses are marketed nationally and internationally by OCULAR SCIENCES Inc. under K020193 cleared for marketing on February 28, 2002.

## 5. CHARACTERISTICS

The characteristics of the HYDROGENICS® 2.0 60 UV ASPHERE (ocufilcon F) Soft (Hydrophilic) Contact Lenses are compared to the characteristics of the predicate device **HYDROGENICS 60 UV Sphere** in the following table.

**TABLE 1**

| Material Comparison | | | | |
|---|---|---|---|---|
| | Predicate Device **HYDROGENICS® 60 UV Sphere and Toric (K992264)** | | Subject device **HYDROGENICS® 2.0 60 UV Asphere** | |
| **PRODUCTION METHOD** | Cast molded process | | Cast molded process | |
| **INTENDED USE** | Daily wear<br>Correction of ametropia | | Daily wear<br>Correction of ametropia | |
| **MATERIAL** | ocufilcon F<br>60% | | ocufilcon F<br>60% | |
| Type | Group IV | | Group IV | |
| Color additive | Vat Blue 6 Dye<br>CFR 130-20-1 | | Vat Blue 6 Dye<br>CFR 130-20-1 | |
| UV additive | Yes | | Yes | |
| Dk permeability, ISO 9913-1 Polarimetric method with edge correction @ 35°C<br>x $10^{-11}$ ($cm^2$/sec) (ml $O_2$/ml x mm Hg) | 25.3 x $10^{-11}$ | | 25.3 x $10^{-11}$ | |
| Light transmittance | Tv, % @ 20°C Illuminant A with a 2° observer (between 380 and 780 nm)<br>97.7% | (between 400 and 800 nm)<br>>95% | Tv, % @ 20°C Illuminant A with a 2° observer (between 380 and 780 nm)<br>97.7% | (between 400 and 800 nm)<br>>95% |

**TABLE 2**

| | Lenses design comparison | | | |
|---|---|---|---|---|
| | Subject Device<br>**HYDROGENICS® 2.0 60 UV ASPHERE**<br>(ocufilcon F) | | Predicate Device<br>**BIOMEDICS® 55 UV Asphere**<br>(ocufilcon D)<br>**K020193** | |
| *Characteristics comparison, -2.00 D* | *Measured* | *Labeled* | *Measured* | *Labeled* |
| Base Curve, mm | 8.5 | 8.5 | 8.4 | 8.6 |
| Diameter, mm | 14.08 | 14.1 | 14.1 | 14.2 |
| Power, D | -1.97 | -2.00 | 2.13 | -2.00 |

## 6. NON CLINICAL STUDIES

In support to this application we are providing

- Additional Manufacturing information
- Finished Lens Parameters comparison with the predicate device
- Labeling Information

By reference: K992264, K020193 and K984046 data can be found concerning:

- Predicate Device
- Chemistry
- Manufacturing process
- Toxicology: lens and packaging materials
- Residual (leachables) Monomer
- Shelf life data
- Microbiology
- Packaging

## 7. CLINICAL DATA

It was determined that Clinical Studies were not necessary to establish the safety and efficacy of the HYDROGENICS®2.0 60 UV ASPHERE (ocufilcon F) Soft (Hydrophilic) Contact Lenses. This determination was based on the following:

- The HYDROGENICS® 2.0 60 UV ASPHERE (ocufilcon F) Soft (Hydrophilic) Contact Lenses were demonstrated to be substantial equivalent to the predicate BIOMEDICS/HYDROGENICS® UV Sphere lenses (K99264 and K984046). All demonstrated substantial equivalence in parameters.
- The HYDROGENICS® 2.0 60 UV ASPHERE (ocufilcon F) Soft (Hydrophilic) Contact Lens design was demonstrated to be equivalent to the predicate Asphere lenses: BIOMEDICS® UV Asphere (ocufilcon D) approved under K020193.

## 8. CONCLUSIONS DRAWN FROM STUDIES

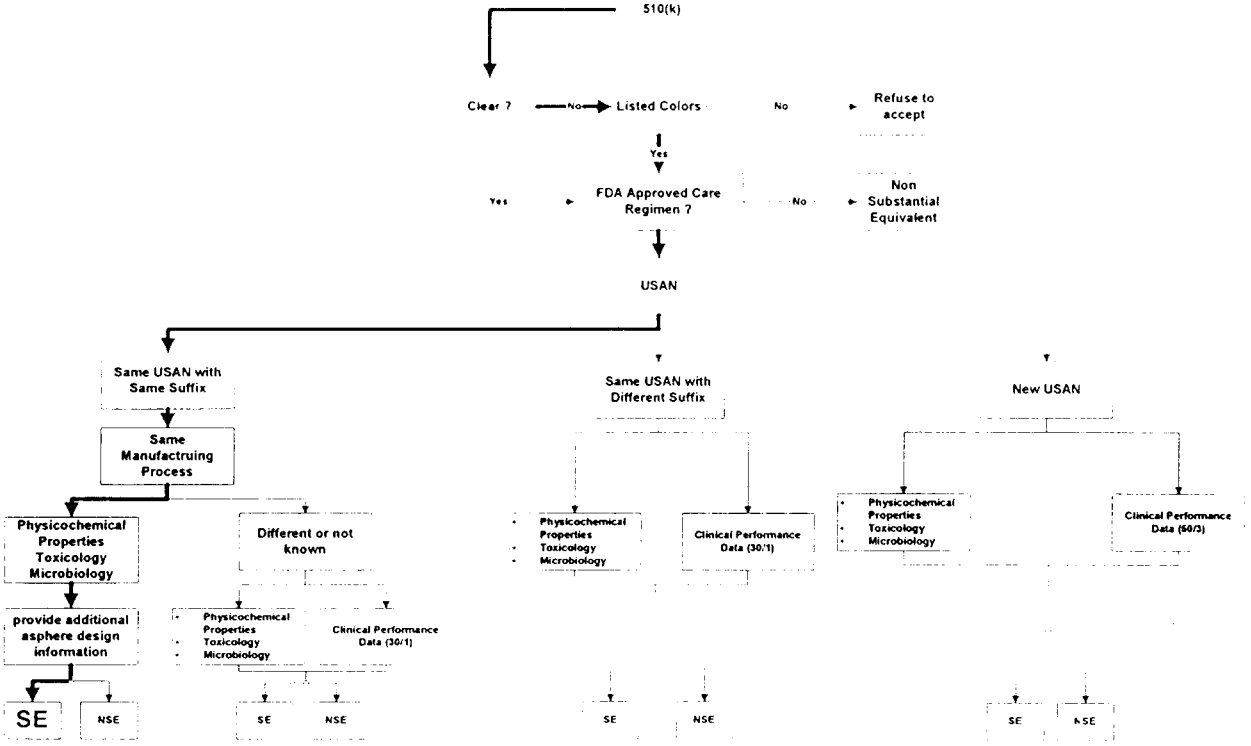
*Substantial Equivalence:*
The information provided in this 510(k) establishes that the HYDROGENICS® 2.0 60 UV ASPHERE (ocufilcon F) Soft (Hydrophilic) Contact Lenses are equivalent in optical, chemical and physical properties of the predicate devices and do not raise any questions of safety and effectiveness. Therefore the device is substantially equivalent to the predicate device.

*Risk and Benefits:*
The risks of the subject device are the same as those normally attributed to the wearing of soft (hydrophilic) contact lenses on a daily wear base. The benefits to the patient are the same as those for other soft (hydrophilic) contact lenses.

## 9. ROUTE CHOSEN IN THE FLOW CHART FOR 510 (K) DAILY WEAR CONTACT LENS

FIGURE 1

HYDROGENICS® 2.0 60 UV ASPHERE



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 18 2003

Ocular Sciences, Inc.
c/o Richard E. Lippman, O.D., F.A.A.O.
R.P. Chiacchierini & Associates, LLC
15825 Shady Grove Road, Suite 30
Rockville, MD 20850

Re: K031477
Trade/Device Name: Hydrogenics® 2.0 60 UV Asphere (ocufilcon F) Soft (hydrophilic) Contact Lenses indicated for Daily Wear
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: Class II
Product Code: LPL; MVN
Dated: May 9, 2003
Received: May 9, 2003

Dear Dr. Lippman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## SECTION 2: INDICATION FOR USE STATEMENT

510(k) Number (if known) K031477

**Device Name:** HYDROGENICS® 2.0 60 UV ASPHERE (ocufilcon F) Soft (Hydrophilic) Contact Lenses

**Indications for Use:**

HYDROGENICS® 2.0 60 UV ASPHERE (ocufilcon F) Soft (Hydrophilic) Contact lenses are indicated for the correction of visual acuity in persons with not-aphakic, non-diseased eyes that are myopic (nearsighted) or hyperopic (farsighted) and may exhibit refractive astigmatism 2.00 diopters or less that does not interfere with visual acuity.

The HYDROGENIC® 2.0 60 UV ASPHERE (ocufilcon F) Soft (Hydrophilic) Contact Lenses are indicated for daily wear. The eye care practitioner may prescribe the contact lenses for either single use disposable wear or for frequent replacement wear. When prescribed for frequent replacement planned replacement the lenses may be disinfected using a chemical or hydrogen peroxide disinfecting systems.

The HYDROGENICS® 2.0 60 UV ASPHERE (ocufilcon F) Soft (Hydrophilic) Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the –counter-use _____

(Division Sign-off)
Division of Ophthalmic Devices

510(k) Number K031477